Minute Order Form (06/97)

United States District Court, Northern District of Illinois

Name of Assigned Judge or Magistrate Judge	Robert W. Gettleman	Sitting Judge if Other than Assigned Judge	
CASE NUMBER	00 C 5791	DATE	July 22, 2003
CASE TITLE	Glaxo Group Ltd. v Apotex, Inc.		

[In the following box (a) indicate the party filing the motion, e.g., plaintiff, defendant, 3rd party plaintiff, and (b) state briefly the nature of the motion being presented.]

MOTION:

DOCKET ENTRY:

(1) ☐ Filed motion of [use listing in "Motion" box above.]
(2) ☐ Brief in support of motion due _____.
(3) ☐ Answer brief to motion due_____. Reply to answer brief due_____.
(4) ☐ Hearing
(5) ☐ Status hearing
(6) ☐ Pretrial conference[held/continued to] [set for/re-set for] on _____ set for _____ at _____.
(7) ☐ Trial[set for/re-set for] on _____ at _____.
(8) ☐ [Bench/Jury trial] [Hearing] held/continued to _____ at _____.
(9) ☐ This case is dismissed [with/without] prejudice and without costs[by/agreement/pursuant to]
☐ FRCP4(m) ☐ General Rule 21 ☐ FRCP41(a)(1) ☐ FRCP41(a)(2).
(10) ■ [Other docket entry]

Plaintiff's motion to release the security bond is granted.

(11) ■ [For further detail see order attached to the original minute order.]

	No notices required, advised in open court.		number of notices	Document Number
	No notices required.			
X	Notices mailed by judge's staff.		JUL 23 2003 date docketed	154
	Notified counsel by telephone.			
	Docketing to mail notices.		docketing deputy initials	
	Mail AO 450 form.			
	Copy to judge/magistrate judge.		date mailed notice	
GDS	courtroom deputy's initials	Date/time received in central Clerk's Office	mailing deputy initials	

U.S. DISTRICT COURT
03 JUL 22 PM 4:17

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

GLAXO GROUP LIMITED, and SMITHKLINE BEECHAM CORP.,	)	
Plaintiff,	)	
	)	No. 00 C 5791
v.	)	
	)	Judge Robert W. Gettleman
APOTEX, INC.,	)	
Defendant.	)	

MEMORANDUM OPINION AND ORDER

Plaintiffs Glaxo Group Limited and SmithKline Beecham Corp. ("plaintiff") sued defendant Apotex, Inc. for a declaration of infringement of patent Nos. 4,562,181 and 4,820,832, and defendant counterclaimed for invalidity. After a lengthy bench trial, the court entered Findings of Fact and Conclusions of Law in plaintiff's favor, concluding that defendant's proposed generic cefuroxime axetil product will infringe the two patents, and permanently enjoining defendant from manufacturing its product for the life of those patents. Glaxo Group Limited v. Apotex, Inc., __ F. Supp.2d ___, 2003 WL 21487161 (N.D. Ill. June 26, 2003).[1] Additionally, the court concluded that defendant willfully infringed the patents, entitling plaintiff to its costs and attorney's fees incurred in prosecuting the suit. Specifically, the court found that defendant "deliberately failed to take due care to respect [plaintiff's] patent rights," and that

[1]A full description of plaintiff's claims and defendant's counterclaims can be found in the court's findings of fact as well as its previous opinions in this case. Glaxo Group Limited v. Apotex, Inc., 130 F. Supp.2d 1006 (N.D. Ill. 2001); Glaxo Group Limited v. Apotex, Inc., 2001 WL 1246628 (N.D. Ill. 2001). Familiarity with those opinions and the terms used therein is assumed.

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defendant filed its ANDA with the intent of putting its antibiotic on the market prior to the expiration of plaintiff's patent. Id. at 18-19.

Defendant has moved pursuant to Fed. R. Civ. P. 59(e) to alter or amend the portion of the court's judgment holding that defendant willfully infringed the patents, which was the basis for the court's ruling that this was an exceptional case entitling plaintiff to an award of attorney's fees. For the reasons set forth below, the motion is denied.

Discussion

Reconsideration under Rule 59(e) is proper only when the court has committed a manifest error of law or fact, or upon discovery of new evidence. In re Prince, 85 F.3d 314, 324 (7th Cir. 1996). Defendant argues that the court made a manifest error of law in finding willful infringement because: (1) the court preliminarily enjoined defendant from making, using, selling, or offering to sell, or importing any other product into the United States, thereby preventing any actual infringement; and (2) the filing of defendant's ANDA cannot constitute an act of artificial or technical infringement under the Drug Price Competitive and Patent Term Restoration Act of 1984, more commonly known as the Hatch-Waxman Act, 35 U.S.C. § 271(e)(2)(A).

"The starting point of every case involving construction of a statutes is the language itself." Blue Chip Stamps v. Manor Drug Stores, 421 U.S. 723, 256 (1975). The provision in question, 35 U.S.C. § 271(e)(2)(A) provides in relevant part:

> (2) It shall be an act of infringement to submit –
>
> (A) an application under Section 505(j) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. § 355(j)] . . . for a drug claimed in a patent or the use of which is claimed in a patent, [ ]

> If the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

It is unquestioned that defendant filed its application for an ANDA under § 505(j) of the Federal Food, Drug and Cosmetic Act ("FDCA"). It is equally unquestioned that the ANDA was for a drug claimed in a patent and that defendant so knew at the time of its application. Finally, it is also unquestioned that the court found that the purpose of defendant's submission was to obtain approval under the FDCA to engage in the manufacturing and sale of defendant's drug prior to the expiration of plaintiff's patent. Because defendant's ANDA falls within the literal language of the Act, the court found that the "filing of the ANDA by [defendant] triggered [plaintiff's] infringement claim and constituted willful infringement . . .." Glaxo Group Limited v. Apotex, Inc., 2003 WL 21487161 at *21.

Defendant argues that this is a manifest error of law because the ANDA itself contained no certification under § 505(j)(2)(A)(vii)(IV) indicating that defendant's purpose in submitting the ANDA was to manufacture or sell its generic product prior to expiration of plaintiff's patent. Resolution of defendant's claim requires an examination of the purpose behind the Hatch-Waxman Act and the particular provision in question.

The Hatch-Waxman Act was passed in 1984 to respond to two problems created by the then-existing statutes that regulated patents and the pharmaceutical industry. Eli Lilly and Co. v. Medronic, Inc., 496 U.S. 661, 669 (1990). The first arose from the fact that inventors ordinarily applied for patent protection for newly discovered drugs well before securing regulatory approval, even though marketing was prohibited until regulatory approval was obtained. Because the Food and Drug Administration ("FDA") generally took much longer to approve an

NDA than the Patent and Trademark Office ("PTO") took to grant a patent, the seventeen year patent term was substantially eroded by the time the patentee could market, and thus profit from, the invention. Id.; Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348, 1357 (Fed. Cir. 2003).

At the same time, generic drug manufacturers were required to obtain an NDA to market a generic product. The new NDA required the generic manufacturer to provide its own independent, safety and efficacy data. Under 35 U.S.C. § 271(a), as held in Roche Products Inc. v. Bolar Pharmaceutical Co., 733 F.2d 858 (Fed. Cir. 1984), however, the manufacture and testing (a use) of a patented product prior to the expiration of the patent was an act of infringement, even if done for the sole purpose of conducting tests and developing the information necessary to apply for an NDA. Eli Lilly, 496 U.S. at 670; Warner-Lambert, 316 F.3d at 1357. Because of the substantial amount of time necessary for the generic manufacturer to obtain data and then secure regulatory approval, requiring those manufacturers to wait until the expiration of the patent to begin testing and other pre-approval activities resulted in a de facto extension of the patent term. Id.

The Hatch-Waxman Act was intended to deal with both of these problems, by restoring to innovators patent time lost during testing and regulatory approval, but enabling generic manufacturers to be ready to enter the market once the patents expired. Generic manufacturers no longer had to prove the safety and efficacy of a drug that was already the object of an NDA. They only had to demonstrate bioequivalence. Id. First, § 201 of the Act, 35 U.S.C. § 156, provided for patent term extension for products "subject to a regulatory review before its commercial marketing or use," if "the permission for the commercial marketing or use of the product after such regulatory review period was the first permitted commercial marketing or use

of the product." Warner-Lambert, 315 F.3d at 1358 (quoting Eli Lilly, 496 U.S. at 676). Patent protection was thus extended to innovative drug manufacturers.

Next, § 202 of the Act added subsection (e)(1) to 35 U.S.C. § 271, which provides that "it shall not be an act of infringement to make, use, or sell a patented invention . . . solely for uses reasonably related to the development and submission of information under a federal law which regulates the manufacture, use, or sale of drugs . . .." The effect of § 271(e)(1) was to partially eliminate the problem of the unintended "de facto" patent term extension, by allowing generic manufacturers to test and seek approval to market the generic form during the patent term. Id.

To further the overall goal of getting generics to market faster, § 101 of the Act amended § 505 of the FDCA (21 U.S.C. § 355), to authorize the filing and approval of ANDAs. Included in the ANDA provision was a method to facilitate adjudication of claims by innovators of infringement or their patents. The mechanism included: (a) provisions for patentees and NDA holders to list patents that claim the approved drug or the approved use of the drug in the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" publication (the "Orange Book"), 21 U.S.C. § 355(b)(1); and (b) a provision requiring ANDA applicants to "certify": (I) that no such patent information is listed, or, if such information is listed then, for each listed patent, (II) that is has expired, (III) that it will expire prior to the ANDA applicant's marketing of the drug, or (IV) that it is invalid or will not be infringed by the manufacture, use or sale of the drug by the ANDA applicant ("a paragraph IV certification"). Id.; 21 U.S.C. § 355(j)(2)(A)(I-IV).

Finally, new Hatch-Waxman § 35 U.S.C. § 271(e)(2)(A) was added to create an artificial act of infringement that consists of submitting an ANDA if the purpose of such submission is to

obtain approval to engage in the commercial manufacture, use, or sale of a drug claimed in a patent before the expiration of the patent, such as an ANDA containing a paragraph IV certification that a listed patent is invalid or that the manufacture, sale, or use of the purposed product would not infringe that patent. Eli Lilly, 496 U.S. at 678.

Thus, the Hatch-Waxman Act was a compromise between the interests of innovative drug manufacturers who had seen the effective term of their patents shortened by the extensive testing and regulatory processes, and the interests of the generic drug manufacturers, whose entry into the market after patent expiration had been delayed by the same regulatory requirements. Warner-Lambert, 316 F.3d at 1358. The Act struck a balance between these two interests. "On the one hand, the manufacture, use or sale of a patented drug is not an act of infringement, to the extent it is necessary for the preparation and submission of an ANDA. On the other hand, once it is clear that a party seeking approval of an ANDA wants to market a patented drug prior to the expiration of the patent, the patent owner can seek to prevent approval of the ANDA by bringing a patent infringement suit." Bristol-Meyers Squibb Co. v. Royce Laboratories, Inc., 69 F.3d 1130, 1132 (Fed. Cir. 1995).

Complicating matters, for purposes of the instant case, is the fact that at the time Hatch-Waxman was passed (1984) the FDCA had a separate section prescribing the regulatory process for approval to market antibiotic drugs. 21 U.S.C. § 357. Thus, the new Hatch-Waxman provisions under 35 U.S.C. § 271(e)(1) exempting from infringement the manufacture, use or sale of a drug for the purposes of developing and submitting information under a "federal law which regulates the manufacture, use or sale of drugs" applied to antibiotics, while § 271(e)(2), which created the artificial act of infringement for seeking the approval of an ANDA under

§505(j) to obtain approval to make, use or sell the generic drug prior to the expiration of the patent on the innovative drug, did not apply to antibiotics.

It is unclear why the FDCA treated antibiotics differently than other drugs, and equally unclear whether Congress recognized the discrepancy when it passed § 271(e)(2). In 1997, however, Congress passed the Food and Drug Administration Modernization Act of 1997 (the "Modernization Act") which repealed 21 U.S.C. § 357. As a result, antibiotics are now treated like any other drug, and generic manufacturers of antibiotics must now apply for ANDAs under § 505(j), which makes 35 U.S.C. § 271(e)(2) applicable. As noted, § 505(j) requires drug manufactures to list patents covering their NDA drugs in the "Orange Book," and also requires generic manufacturers to include patent certification in their ANDA pursuant to 35 U.S.C. § 355(j)(2)(A)(vii)(I-IV). Section 357 of the FDCA did not include such requirements for antibiotics, however, and the Modernization Act exempted drug manufacturers who had filed previously under § 357 ("old antibiotics") from Orange Book listing requirements, and also exempted ANDA applicants for generic versions of old antibiotics from the certification requirements under § 355(j)(2)(A)(vii).

Because cefuroxime axetil is an "old antibiotic," the patents claiming it are not listed in the Orange Book. Therefore, even though cefuroxime axetil was claimed in a patent, and defendant knew that when it filed its ANDA, defendant was not required to provide a certification under § 355(j)(2)(A)(vii). In particular, despite fully intending to go to market prior to the expiration of plaintiff's patent, defendant was not required to file a paragraph IV certification that the patent was invalid or would not be infringed by the use, manufacture, or sale of the new generic drug. It is this certification, according to defendant, that creates the "artificial

act of infringement" under § 271(e)(2). Defendant argues that, absent the certification and, therefore, the artificial infringement under § 271(e)(2), it has not literally infringed the patent (this court enjoined defendant from manufacturing, using or selling in the United States until expiration of the patent) and thus cannot be subject to an award of attorney's fees for willful infringement.

Defendant's "certification" argument is based predominately on the Supreme Court's discussion of § 271(e)(2) in Eli Lilly. After reviewing the history and purpose of § 271(e)(2), as set forth above, the Court noted that the statutory scheme would not work if the holder of a patent on a pioneer drug was disabled from establishing in court that there had been an act of infringement (because § 271(e)(1) authorized the manufacture, use or sale for purposes related to submitting the information required for the ANDA). Therefore, according to the Supreme Court, § 271(e)(2) created "a highly artificial act of infringement that consists of submitting an ANDA or paper NDA containing the fourth type of certification that is in error as to whether commercial manufacture, use or sale of a new drug (none of which, of course, has actually occurred) violates the relevant patent." Eli Lilly , 496 U.S. at 678.

It is the passage quoted above that, according to defendant, demonstrates that without a paragraph IV certification there can be no artificial act of infringement under § 271(e)(2). This court does not agree, however, that the Supreme Court's statement can be so read. First, the statement is not part of the holding. In Eli Lilly, the court addressed the question of whether § 271(e)(1) could be read broadly to cover medical devices rather than simply drugs. The Court of Appeals had held that it did, and the petitioner then argued to the Supreme Court that "the argument for a broad construction of Section 271(e)(1) is reputed by the companion Sections

(e)(2) and (e)(4)." It was in response to this argument that the Supreme Court set forth its review of § 271(e)(2) and the need for an artificial act of infringement "for a very limited and technical purpose that related only to certain drug applications," Id. at 677, ultimately concluding that "[q]uite obviously, the purpose of subsections (e)(1) and (e)(4) is to enable the judicial adjudication upon which the ANDA and paper NDA schemes depend. It is wholly to be expected, therefore, that these provisions would apply only to applications under which the sections establishing those schemes – which (entirely incidentally, for present purposes) happen to be sections that relate only to drugs and not to other products." Id. at 678 (emphasis in original).

It is clear from the Court's discussion that the only issue before it was whether § 271(e)(1) covered medical devices other than drugs. What constitutes infringement under § 271(e)(2), and whether a paragraph IV certification is necessary before § 271(e)(2) can apply, were not before the court. Indeed, reading Eli Lilly literally as suggested by defendant, the holding would be that infringement occurs under § 271(e)(2) only when the ANDA contains a paragraph IV certification that "is in error as to whether the commercial manufacture, use or sale would violate the relevant patent." Id. That cannot have been the Court's intent, however, because the artificial act of infringement creating a case or controversy sufficient to support subject matter jurisdiction for a court to hear the ultimate infringement issue is the filing of the ANDA, not whether the certification was correct or incorrect. "Thus, § 271(e)(2) provided patentees with a defined act of infringement sufficient to create case or controversy jurisdiction to enable a court to promptly resolve any dispute concerning infringement and validity." Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562, 1569 (Fed. Cir. 1997).

Moreover, Eli Lilly was written in 1990, predating the Modernization Act by seven years. Obviously, the Court's discussion was not intended as a "prediction" that the filing of an ANDA for an "old antibiotic" without a paragraph IV certification but with the intent to market prior to expiration of the patent on the pioneer drug would be insufficient under § 271(e)(2) to create a case or controversy, since there was as yet no such thing as an "old antibiotic." Accordingly, this court rejects defendant's position that under Eli Lilly, a paragraph IV certification is the linchpin to case or controversy jurisdiction under § 271(e)(2).

Neither party has presented the court with any legislative history indicating why antibiotics were originally treated differently than other drugs or, when the Modernization Act was passed, "old antibiotics" were not added to the Orange Book and certification by generic manufacturers was exempted. Defendant's position, however, runs afoul of one of the two stated goals of the Hatch-Waxman Act when initially passed. Under defendant's position, generic manufacturers of "old antibiotics" may take advantage of § 271(e)(1), and manufacture, use or sell a drug if done solely for the submission of an ANDA without violating the pioneer patent, but the patent holder must wait until the generic drug actually goes to market before bringing suit for a judicial determination that the generic infringes the patent.

That complies with the goal of eliminating the de facto patent extension, but essentially eviscerates the pioneer's incentive by eliminating its ability to protect its patent prior to actual infringement. Defendant has presented nothing to suggest that this is what Congress intended, and the fact that new antibiotics are now treated like all other drugs suggests otherwise.

That brings the court full circle, back to the plain wording of § 271(e)(2), which provides that the submission of an application under § 355 of the FDCA is an act of infringement if the

purpose is to obtain approval to engage in the commercial manufacture, use or sale of a drug claimed in a patent before the expiration of that patent. That is exactly what defendant did. Therefore, the court concludes, as it did before, that defendant's ANDA application triggered a violation of § 271(e)(2). Because the court found that defendant's actions were made knowing that its product would infringe plaintiff's patents, the infringement was willful, warranting an award of attorney's fees. Defendant's motion to alter or amend the judgment is, therefore, denied.

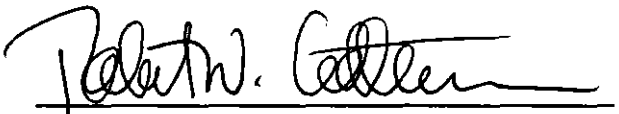
Defendant has also filed a motion to postpone proceedings with respect to attorneys' fees pending the appeal of the court's judgment to the United States Court of Appeals for the Federal Circuit. Plaintiff opposes this motion, arguing that it is prepared to comply with the requirements of Local Rule 54.3 governing fee petitions. The court finds defendant's logic persuasive in this regard. Should defendant prevail on appeal, on either the merits of the infringement issue or the willfulness issue, plaintiff's fee petition is likely to become moot. Should plaintiff prevail on appeal (as this court predicts), its fee petition will be altered by the time spent on the additional proceedings. Accordingly, the court in the exercise of its discretion grants defendant's motion to postpone and stays further proceedings on plaintiff's fee petition until conclusion of the appeal.

Finally, plaintiff has filed a motion to release the security bond that it posted to secure the preliminary injunction that was entered by this court and affirmed by the Federal Circuit. As Judge Posner noted in Ty, Inc. v. Publications International, Ltd., 292 F.3d 512, 516 (7th Cir. 2002), "The purpose of an injunction bond is to compensate the defendant, in the event he prevails on the merits, for the harm that an injunction entered before the final decision caused

him, and so it is required only for a temporary restraining order or a preliminary injunction, Fed. R. Civ. P. 65(c), not for a permanent injunction."

Because this court has issued a permanent injunction prohibiting defendant from infringing plaintiffs' patent in this action, the need for an injunction bond has vanished. Plaintiff's motion to release the security bond is granted.

ENTER: July 22, 2003



Robert W. Gettleman
United States District Judge